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(54) Title: DOSAGE FORM WITH A CORE TABLET OF ACTIVE INGREDIENT SHEATHED IN A COMPRESSED ANNU-LAR BODY OF POWDER OR GRANULAR MATERIAL, AND PROCESS AND TOOLING FOR PRODUCING IT

(57) Abstract: A solid dosage form for oral administration to a patient comprising a core tablet sheathed in an annular body of compressed powder or granular material is provided. A preferred embodiment of the solid dosage form reduces contact of the active ingredient in solid form with the mucosa lining the gastrointestinal tract, which is particularly advantageous for delivering an ulcerative drug. A tool set comprising a columnar punch and a punch assembly comprising an annular punch and core rod, and a tableting process for making the solid dosage form are also provided.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/36081

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) :A61K 9/24, 9/28, 9/30; B29C 43/20; B30B 11/08  
 US CL :Please See Extra Sheet.

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/472, 473, 474, 475; 264/112, 123; 425/344, 345, 352, 353, 354

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST search terms: annular body, manesty toolset, toolset, annular punch and die, columnar punch, tablet sheath, compressed powder tablet core, die bore

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,264,985 B1 (CREMER) 24 July 2001, see figures 1-4, claims 1-11.	1-19, 25-38
A	US 6,620,358 B2 (VOSS) 16 September 2003, see claims 1-13.	25-38
Y	US 1,609,460 (BUTTLES) 07 December 1926, see entire document.	20-24
Y	US 3,149,375 (GEHL) 22 September 1964, see entire document.	20-24
Y	US 5,074857 (SHEPHERD et al) 24 December 1991, see figure 1, claims 1-15.	1-4
Y	US 5,088,915 (KORSCH et al) 18 February 1992, see column 2, lines 25-65.	25

Further documents are listed in the continuation of Box C.

See patent family annex.

• Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance		
"E" earlier document published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

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**INTERNATIONAL SEARCH REPORT**International application No.  
PCT/US02/36081**A. CLASSIFICATION OF SUBJECT MATTER:**  
US CL :

424/472, 473, 474, 475; 264/112, 128; 425/344, 345, 352, 353, 354

**BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING**  
This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 18.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claim(s) 1-19, drawn to a solid pharmaceutical dosage form.

Group II, claim(s) 20-24, drawn to a toolset.

Group III, claim(s) 25-38, drawn to a process for producing a pharmaceutical dosage form comprising forming an annular body.

The inventions listed as Groups I, II, and III do not relate to a single inventive concept under PCT Rule 18.1 because, under PCT Rule 18.2, they lack the same or corresponding special technical features for the following reasons: The listed inventions lack unity of invention under PCT Rules 18.1 to 18.2 because there is no special technical feature which links a pharmaceutical dosage form capable of being produced by various conventional formulation methods. Regarding the toolset of claims 20-24, while it may be specific for a particular solid form's configuration, it is not critical for forming the solid dosage form of claims 1-19, other appropriate apparatus and means recognized in the art would also be suitable. The process of claims 25-38 is but one of many processes for producing dosage forms as in claims 1-19 and is not considered particularly limited to pharmaceuticals nor does it require the toolset of claims 20-24. Since neither group II or Group III is connected to the main invention they are considered separate inventions.

**INVITATION TO PAY ADDITIONAL FEES**

International application No.

PCT/US02/36081

1. This International Search Authority has found 9 inventions claimed in the International Application covered by the claims indicated below:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 18.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claim(s) 1-19, drawn to a solid pharmaceutical dosage form.

Group II, claim(s) 20-24, drawn to a toolset.

Group III, claim(s) 25-38, drawn to a process for producing a pharmaceutical dosage form comprising forming an annular body.

and it considers that the International Application does not comply with the requirements of unity of invention (Rules 18.1, 18.2 and 18.3) for the reasons indicated below:

The inventions listed as Groups I, II, and III do not relate to a single inventive concept under PCT Rule 18.1 because, under PCT Rule 18.2, they lack the same or corresponding special technical features for the following reasons: The listed inventions lack unity of invention under PCT Rules 18.1 to 18.2 because there is no special technical feature which links a pharmaceutical dosage form capable of being produced by various conventional formulation methods. The toolset of claims 20-24, while it may be specific for a particular solid form's configuration, is not critical for forming the solid dosage form of claims 1-19. The process of claims 25-38 is but one of many processes for producing dosage forms as in claims 1-19 and is not considered particularly limited to pharmaceuticals nor does it appear to require the toolset of claims 20-24. Since neither group II or Group III is connected to the main invention they are considered separate inventions.